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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,432	12/30/2003	Charles R. Roe	BHCS:1006RCE	7856
34725	7590	12/31/2007		
CHALKER FLORES, LLP 2711 LBJ FRWY Suite 1036 DALLAS, TX 75234			EXAMINER POLANSKY, GREGG	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/748,432

**Applicant(s)**

ROE, CHARLES R.

**Examiner**

Gregg Polansky

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-18 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18 and 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Claims**

1. The terminal disclaimers filed on 10/13/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Numbers 10/371385 and 10/748495 have been reviewed and are accepted. The terminal disclaimer has been recorded.
2. Claims 15-18 and 21-36 are pending.
3. Claims 15-18 and 21-36 are presently under consideration.

### ***Claim Objections***

4. Claims 21-23 are objected as improper dependent claims because they refer canceled Claims 19 and 20.
5. Claims 24-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

### ***Claim Rejections - 35 USC § 112***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 15-18 and 21-36 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for accelerating the growth rate of a prematurely-born human infant with triheptanoin, does not reasonably provide

enablement for any seven carbon fatty acids or derivative thereof (straight or branched chain of seven carbons with any substitution). The Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims. In this regard, the application disclosure and claims have been compared per factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant Specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to methods of accelerating the growth rate of a prematurely-born human infant by administering to said infant a composition comprising

a seven carbon fatty acid or derivative thereof; and wherein the said infant rapidly obtains nutrition from odd carbon fatty acid  $\beta$ -oxidation metabolism, and wherein said composition is adapted for consumption in one or more dosage from about 15% to 40% of the dietary caloric requirement for said infant for 24 hours.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the neonatology.

The present invention is unpredictable with respect to the administration of any "derivative" of any seven-carbon chain fatty acid.

The breadth of the claims

The claims are very broad and inclusive to any seven-carbon fatty acids or derivatives (straight or branched chain of seven carbons with any substitution).

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to an *in vitro* cell culture assay of cells derived from a deceased infant, a single cell culture derived from a fetus, and a single *in vivo* example treating an infant with triheptanoin-supplemented formula only. There is no showing drawn to the critical elements of a predictable acceleration of growth rate of a prematurely-born human infant, wherein said infant obtains nutrition from odd carbon fatty acid  $\beta$ -oxidation and wherein the composition comprising said seven-carbon chain fatty acid is adapted for consumption in one or more doses and said doses comprise 15%-40% of the dietary caloric requirement for said infant for 24 hours.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how unknown derivatives of any seven-carbon fatty acids (straight or branched chain of seven carbons with any substitution) are used to accelerate the growth of prematurely-born human infants. The level of experimentation needed to determine possible derivatives, such as amides or esters, is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

### ***Conclusion***

8. Claims 15-18 and 21-36 are rejected.
9. No claims are allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Application/Control Number:  
10/748,432  
Art Unit: 1614

Page 6

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gregg Polansky

Phyllis Spivack  
PHYLLIS SPIVACK  
PRIMARY EXAMINER

12/23/07